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EDWARD J. SCHWARTZBAUER
(612) 340-2825

April 30, 1985

Honorable Crane Winton
1307 Mount Curve Avenue
Minneapolis, Minnesota 55403

Re: U.S.A., et al. v. Reilly
Tar & Chemical Corp., et al.

Dear Judge Winton:

I am enclosing a copy of a recent article on cancer risk assessment published in the December 1984 EPRI Journal. I thought you would be interested in reading an objective review which resulted from a recent panel discussion by participants of industry, government and universities.

Very truly yours,

Edward J. Schwartzbauer

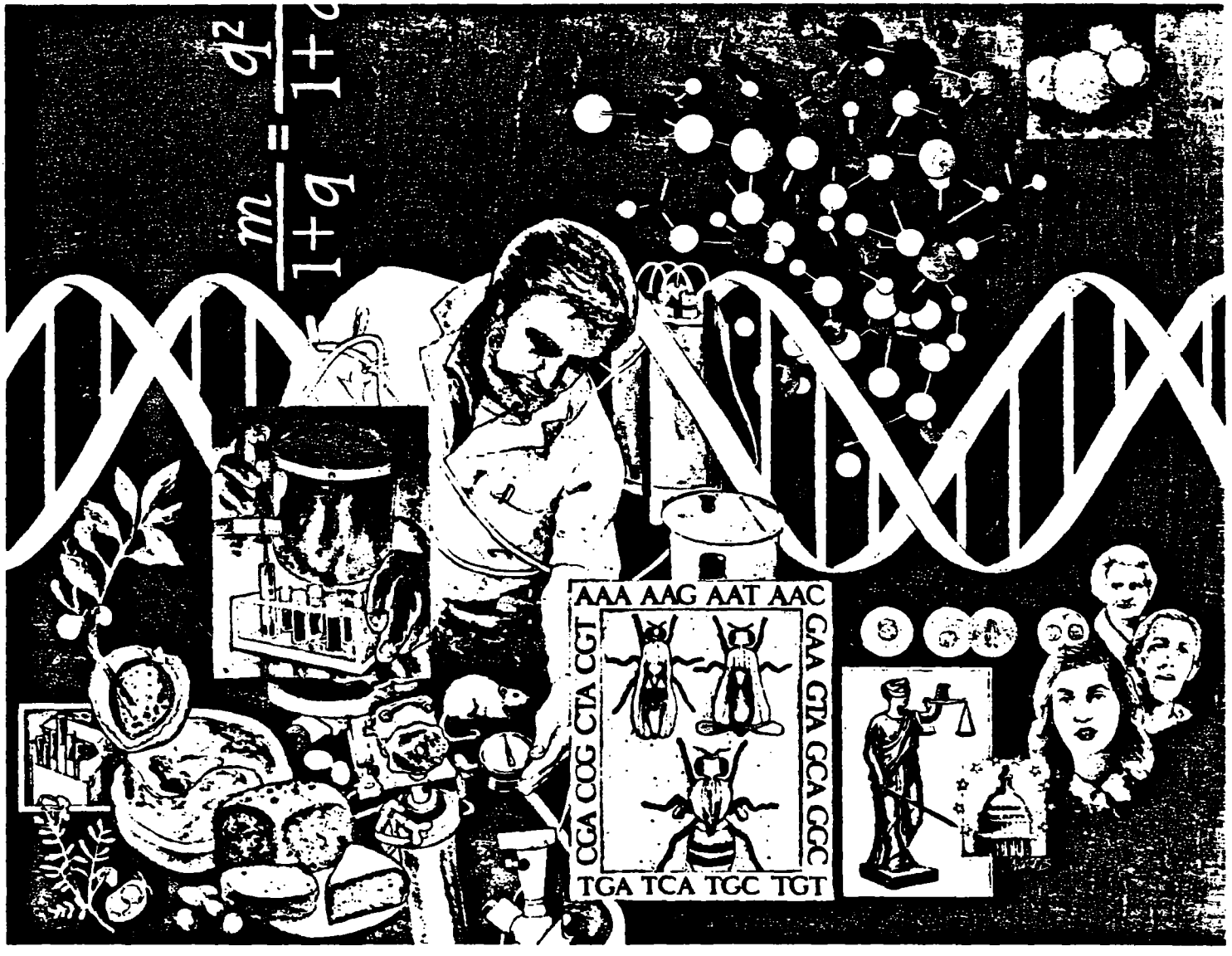
EJS:ml
Enclosure

cc: All Counsel of Record
Robert Leininger, Esq.
Paul G. Zerby, Esq.

by Brent Barker

Cancer and the Problems of Risk Assessment

The question of how to quantify and communicate risk in the modern world has great implications for public acceptance of science and industry. The latest meeting of EPRI's Advisory Council, featuring talks by nine experts in the field, used cancer as a focus to dissect the difficulties of risk analysis.



Conventional wisdom 25 years ago held that cancer-causing substances were rare and ultimately controllable, that the sources of the disease would someday be isolated and eradicated. The model was not unlike that of many large communicable diseases that had been brought under control by twentieth-century medicine. But as scientific exploration advanced through the 1960s and 1970s, the known and suspected sources of cancer expanded rather than narrowed, and the mechanisms of the disease grew more complex rather than more simple.

As headlines bannered each newly discovered cancer-causing compound—in what became known cynically as the carcinogen of the week—the old hope gave way to fear and fear to mounting pressure on the political and legal systems for protection and compensation. Eventually, ideology began to suffuse fact in an interpretive scramble to replace simple cause with simple blame, and by the mid 1970s industry was popularly indicted. It seemed a fitting notion to a society newly infatuated with things natural that it would be the things synthetic that would cause cancer.

Today, conventional wisdom inclines toward the belief that cancer, like a case of the disease itself, is growing out of control, perhaps even heading toward epidemic proportions and that it is all fundamentally due to new risks imposed by our industrial base, risks resulting from our post–WW II profusion of man-made chemicals, pesticides, plastics, food additives, radiation sources, and the like.

Although science in recent years has acquired new information that promises once again to turn conventional wisdom upside down, the deep dread of cancer, combined with its presumed link to industry, has brought about an explosive public health issue, one in which enormous social forces are now being unleashed. For all practical purposes the courts and the regulatory bodies are now under siege, and the liability issues threaten to drain the resources of producers and insurers alike.

It was against this backdrop that the EPRI Advisory Council drew together 50 participants from industry, government, and universities to discuss the interdisciplinary nature of technology risk assessment and, in particular, to focus on the critical issues surrounding cancer risk from exposure to toxic substances.

Although the utility industry is not at the center of this storm, it does have a broad interest in the development of risk assessment methodology. And because cancer embodies virtually all the societal concerns over risk in the modern world, it was considered by the meeting organizers to be a useful focal point for illuminating the larger sphere of risk assessment.


Bruce Ames

"Nature is not benign. It's full of nasty things. There are large numbers of carcinogens and mutagens in every meal, all perfectly natural and traditional. My own estimate is that we eat about 10,000 times more of these natural pesticides than we do of man-made pesticides."

At the Hyatt Del Monte in Monterey, California, nine invited speakers led off the three days of vigorous exchange on the scientific knowledge of cancer risk, the legal and societal response to risk, and risk management policy. Time and again the discussion returned to the emerging field of quantitative risk assessment, with the participants in clear agreement that not only do the numbers matter (given the enormous range in both carcinogenic potency and exposure), but the numbers themselves will someday lead to and support new language for communicating the broad spectrum of risk to the general public. Currently, the public has no frame of reference, and so when confronted with a new carcinogen, it cannot separate a significant risk from a trivial risk.

Cancer risk in perspective

Bruce Ames, chairman of the biochemistry department of the University of California at Berkeley, lent some much-needed perspective to the area of cancer risk by dispelling the myth of an ongoing epidemic and by summarizing some critical new information about natural carcinogens, the role of diet and metabolism in cancer, the human defense mechanisms, and a possible link with aging.

One out of four in the United States now dies of cancer, and when the historical statistics are adjusted for the increasing longevity of the U.S. population, the same was apparently true 50 years ago. With the exception of lung cancer, which has clearly increased because of cigarette smoking, cancer rates have held constant or have declined over the last 5 decades. "This strongly suggests that whatever is causing cancer has been around a long time," said Ames, "and the epidemiologic work by R. Doll and R. Peto indicates that our industrial pollution doesn't play a major role, probably less than a few percent." He went on to say that because cancer rates by type vary from culture to culture (Japanese are relatively higher in stomach cancer and Americans in colon and breast cancer), environmental factors in the broadest sense became suspect and, after considerable searching, narrowed down to what should have been obvious from the beginning: the human diet.

Ames recalled that Sugimura in Japan, knowing about the mutagenicity of cigarette tar, made a mental connection,

scraped some brown and charred material from the fish cooking on his grill, used a quick bioassay test, and found it highly mutagenic (and presumably carcinogenic). Subsequent work in Japan and the United States revealed that virtually all burnt and browned material contains carcinogens—from auto exhaust to cooked protein to coffee to caramelized sugar—and that it is through the diet that the greatest quantities are normally ingested. Ames indicated, for example, that the daily intake of burnt and browned material from cooked foods is typically several times greater than that taken in by a heavy smoker, although it could well be that the lungs are more sensitive to carcinogenic material than the stomach.

Plants, another staple of the human diet, are also filled with mutagens and carcinogens. Without the ability to run from predators, plants have evolved a form of chemical warfare to ward off fungi, insects, and the like. Ames pointed out that plants are 2–10% by weight toxic chemicals and cited a lengthy list of compounds found in ordinary foods, from black pepper and mustard to mushrooms, celery, and some herbal teas, whose natural pesticides are known carcinogens. One additional wrinkle of the plant's protective mechanism is that when damaged or bruised, it increases its toxic output (of the same or different chemicals), often by 100 times or more. "Nature is not benign," said Ames, "It's full of nasty things. There are large numbers of carcinogens and mutagens in every meal, all perfectly natural and traditional. My own estimate is that we eat about 10,000 times more of these natural pesticides than we do of man-made pesticides."

Protecting us from this carcinogenic onslaught, which extends beyond our food to chemicals of all types and even to sunlight and oxygen, is an elaborate three-tiered defense. The first defense is that "we are partially disposable . . . every day we slough off the lining of our mouth, stomach, colon, intestine." The second line of defense is biochemical, an elaborate system of enzymes, designed principally to counteract the effects of toxic substances. Here the diet plays a vital role in supplying so-called anticarcinogens, such as beta-carotene, vitamin E, and selenium. The third line of defense occurs after the first two are breached and some of the damage is done: repair enzymes run up and down the DNA helix looking for damage and snipping out the damaged part. Some enzymes repair any break they encounter, others are coded to look only for a specific (and presumably very important) type of damage. But the onslaught is enormous. On the basis of his analysis of the discards of repaired-out DNA in the urine, Ames estimated that "thousands of hits are made on the DNA of each cell every day."

Jeffrey Harris

"Can we screen all these chemicals, and what are the implications of doing so? Being compelled to assess chemicals on a case-by-case basis, forward risk assessment operates in a world where false positives [falsely indicated cancer] or trivial true positives can have large social costs."

How then, given this flux of genetic damage, have we managed to survive at all? Undoubtedly, the body's defense mechanisms are of major importance. Ames believes that although the full answer still lies before us, through the use of recombinant-DNA tools science is crossing a new threshold of understanding and that the causes of the major human cancers will be understood in the next decade. "Biology is going like a rocket," he said, "and things are going to turn out to be very different from what people think." He finds particularly intriguing that aspect of cancer that may be bound up with the aging process, and believes that "a big contribution to cancer will turn out to be our own metabolism."

In this regard, one innovation during primate evolution that probably helped us evolve from a short-lived to a long-lived creature was a slower metabolic rate (rats, for example, with a much faster metabolic rate, begin to succumb to tumors after 2 to 3 years, just as humans do in their 70s and 80s). By reducing the metabolic rate we reduce oxygen intake and in turn the flux of so-called oxygen radicals, which Ames thinks could be an important contributor to both cancer and aging. With free electrons available, these radicals bond to and damage DNA; thus, oxidation, which causes fats to go rancid and metals to rust, appears to be a fundamental destructive process in human beings as well. We breathe in 21,000 liters of air each day, and as the oxygen accepts electrons in the formation of water, it goes through several intermediary stages (hydrogen peroxide, hydroxyl radicals) that are known mutagenic and carcinogenic compounds.

What Ames has succeeded in painting could be thought of as our natural carcinogenic background against which newly found carcinogenic risks can and should be compared. He points out that nature's pesticides typically come in parts-per-hundred or parts-per-thousand concentrations and impose measurably greater risks than the parts-per-billion controversies that have characterized some of the great public scares in recent years, such as ethyl dibromide (EDB) in grain products and trichloroethylene in the well water of Silicon Valley (California). Both of these he

claims are less risky in terms of carcinogenesis than drinking a glass of ordinary tap water (because of chloroform from chlorination) or eating a peanut butter sandwich (because of aflatoxin). Such risks typically cannot be separated from the carcinogenic background and are trivial compared with such things as cigarette smoking, which accounts for 30% of cancer deaths in the United States as well as 25% of fatal heart attacks.

Defining and measuring the link

Many people die of cancer, and the fact that there are tens of thousands of potential cancer-causing agents (including our own metabolism) makes the linkage between a specific cancer and a specific exposure highly tenuous. At best it comes down to a probability surrounded by some carefully crafted measure of uncertainty; at worst, just someone's guess. Some diseases, such as asbestosis, have such a unique symptomatic signature that the probability of causation approaches 100%; but with most cancers the source could be any one of thousands of possible carcinogens.

Compounding the problem of pinpointing a specific cause are the long latency of most cancers (20–30 years), during which many other exposures and stresses take place; the amplification of cancer risk by multiple agents (e.g., asbestos plus smoking, or smoking plus drinking); and the possibility that cancer is not just an either/or disease but rather a progression through several distinct stages, with each stage requiring its own initiator or cause (the so-called multistage model).

Despite the complexities, it is the business of the risk assessment field to extract the factual basis of such risk, to seek proper definition of the risk, and, if possible, to put a number to it. In the elusive world of cancer causation, the traditional methods of gathering facts have been epidemiologic studies, which look for the statistical differences in human populations, and animal studies in controlled laboratory tests. Both are slow and expensive. Animal studies, for example, now cost about $500,000 for each chemical tested, can take years, and can introduce great uncertainty when the results are finally extrapolated from rats to human beings.

As a result, risk estimates are less than precise, and relatively few chemicals have been tested for carcinogenicity in animals. In 8 years, the National Cancer Institute and the National Toxicology Program have only tested some 200 compounds, the bulk of which were man-made chemicals. About 10 years ago, another fundamental tool, the short-term bioassay test, was added. This allows for a quick (48-hour) test of mutagenicity by counting bacterial colonies in a Petri dish. Sometimes referred to as the Ames test after its pioneer, the procedure has vastly expanded the ability of science to explore the toxicity of the real world. Over 3000 laboratories in the world are now using the Ames test and other short-term bioassays.

Warner North

"How can we develop a process that the public can trust? We can bring together the best of science in risk assessment but we are still left with a range of uncertainty, debate, and disagreement, and then critical concepts get lost when a number goes in a public document. I think there is real danger in one seemingly blessed number ending up in a report."

Jeffrey Harris, M.D., associate professor of economics at MIT, addressed the strengths and weaknesses of the field (and its tools) by dividing risk assessment into two basic approaches: forward (e.g., laboratory) and backward (e.g., epidemiology). "In forward risk assessment, we start with a large collection of potentially carcinogenic agents and try to determine which ones cause cancer, and if so, how much cancer. . . . Here we are supposed to find an efficient means of reducing 10,000 potentially carcinogenic agents to perhaps a few dozen important ones. Can we screen all these chemicals, and what are the implications of doing so? Being compelled to assess chemicals on a case-by-case basis, forward risk assessment operates in a world where false positives [falsely indicated cancer] or trivial true positives can have large social costs." Given the charged atmosphere surrounding anything labeled cancer-causing, the danger Harris sees is that forward risk assessment can send us off on some very expensive goose chases, reacting to everything that shows up positive in a laboratory.

"In backward risk assessment," said Harris, "we start with a large collection of cancer cases and try to determine what caused them. . . . The data are poor, difficult to collect, and only gross truths come out. But the main benefit of looking at the human experience and working backward is that interesting hypotheses are formed that are not created by moving forward. We observe, for example, that the most significant trend in cancer incidence is the marked, continuing rise in lung cancer, especially that now occurring among women. . . . We also see that while the incidence of breast cancer in Japan is relatively low, the rate among Japanese women who migrate to Hawaii is four times greater—that is, much closer to the breast cancer rate among Hawaiian whites."

Harris believes that despite its bad reputation, epidemiology is an important tool and one vastly underused. He sees its real significance as providing major clues, new ideas, and above all, the big picture. It was, after all, backward risk assessment techniques that established

and defined the risks of radiation, tobacco, and asbestos.

Nevertheless, the shortcomings and scientific frustrations of the risk assessment field drew fire throughout the three-day conference. Karim Ahmed, senior scientist and research director for the Natural Resources Defense Council, said, "I'm skeptical of quantitative risk assessment, at least in the cancer field. The science is too imperfect, and the results are likely to be used literally, because all the caveats get lost."

Warner North, principal of Decision Focus, Inc., expressed similar concern about how to meaningfully convey the uncertainty surrounding quantitative risk assessments. "I'm awed," he said, "by the magnitude of the problem facing us. How can we develop a process that the public can trust? We can bring together the best of science in risk assessment, but we are still left with a range of uncertainty, debate, and disagreement; and then critical concepts, such as plausible upper bound, get lost when a number goes into a public document. I think there is real danger in one seemingly blessed number ending up in a report."

The uncertainty in risk estimates stems in part from using animals as surrogates for humans, because there can be orders of magnitude difference in the carcinogenic potency of a given substance among different species. And it was in this vein that Laurence Moss, a consultant with Energy Design and Analysis, Inc., recalled the different reactions to unleaded gasoline, and asked facetiously "whether a man is more like a mouse or more like a rat." North responded, "The issue is, in fact, crucial because it makes a great deal of difference in the estimate we get. One of the worst-case assumptions built into the EPA procedures is that they use the most sensitive species, and there are situations where we have reason to believe that the most sensitive species may not be representative of the way the human metabolism works."

Milton Russell, assistant administrator for policy, planning, and evaluation at EPA, added that "depending on which animal you use, and whether you use a model that uses surface area or weight, you can get a difference in risk of up to 39,000 times." He went on to add that uncertainties in the risk assessment process are multiplied (not added) and in the case of cancer risk this leads to extreme conservatism in the decision-making process. "If you are relatively sure of the probability of risk, like automobile accidents, the range of uncertainty is narrow, and the difference between a plausible upper bound and a maximum likelihood and a plausible lower bound is relatively small. But if you are quite uncertain (as we are in many of these health effects), the range between this upper and lower bound is very, very large. Multiplying the large uncertainties associated with each factor in the estimate leads to cascading conservatism in decision making."

William Thilly

"Each mutagen leaves a recognizable fingerprint, a unique pattern of mutation on the DNA of the cell population that we can read. We think we're close to developing the technology that permits this analysis on a single blood sample."

Reflecting on the various dilemmas of cancer risk assessment, including the impossibility of ever proving that something is not a carcinogen, Arthur Upton, professor at the New York University School of Medicine and former director of the National Cancer Institute, said, "Epidemiologic evidence is long in coming and relatively insensitive. And animal systems are not altogether predictive: We know that the rat only predicts the mouse 80% of the time and vice versa, and that the rodent may miss an important human carcinogen altogether." Ahmed added, "Major uncertainties arise not only from animal-to-human extrapolations but also from the different theoretical cancer models assumed in the estimates." And Alvin Weinberg, director of the Institute of Energy Analysis of Oak Ridge Associated Universities, concluded, "We may be dealing with issues that transcend today's science."

Given its lack of precision, Chauncey Starr, vice chairman and founding president of EPRI, suggested that quantitative risk assessment be viewed as much as a process for clarifying thought and ensuring dialogue as for any particular number it might produce. "It forces full disclosure of assumptions, precepts, and biases of all parties to the process," he said. "It also reveals all secondary interactions, including the benefits derived from taking a technological risk, so that we end up with the most rational means of allocating public resources. . . . We must be patient with the process, recognizing that we are in the infancy of an art. Quantitative risk assessment will improve with time; right now it's just a rough guide but still better than someone's guesswork."

One thing that may come with time, perhaps even in the next few years, is a powerful new tool for risk assessment, one that might reduce the uncertainties by providing direct access to the human beings at risk. William Thilly, professor of genetic toxicology at MIT, believes that indirect, subjunctive means of estimating hazards, such as animal models or cell assays, will not be sufficient. Instead, he proposes developing techniques that have the capability of directly measuring (through the blood or urine) genetic damage in humans resulting from some

exposure to agents that react with and change human genetic material. He and his colleagues at MIT have found that each chemical mutagen causes genetic change in human cells grown in a laboratory in precise, unique, and repeatable ways. For the last year they have been trying to develop a molecular recognition technique (denaturing gel electrophoresis) to get at these patterns in human blood samples. Said Thilly, "Each mutagen leaves a recognizable fingerprint, a unique pattern of mutation on the DNA of the cell population that we can read. We think we're close to developing the technology that permits this analysis on a single blood sample. Our goal, which we believe to be wholly feasible, is to be able to differentiate chemically induced changes from spontaneous changes. The method should be applicable to identifying major chemical mutagens should it be discovered that cells in humans suffer predominantly nonspontaneous changes."

A direct measurement tool, such as Thilly's work promises, could not come at a more opportune time. It may help to tighten the cause and effect linkage at a time when court cases are mushrooming; to refute false claims of damage; to allay the mental distress of exposed populations; and to give risk assessment a sounder footing in future policy analysis, compensation and litigation actions, as well as in the business of allocating scarce public health resources. It comes at a time of mounting public fear and pressure, at a time when the federal government, for example, has just embarked on a full-scale investigation of the effects of Agent Orange that will cost $100 million and run through the end of the century.

Although physical effects on the Vietnam veterans or their offspring have not yet emerged, anxiety has emerged as a fundamental driving force. The *New York Times* recently cited a University of Minnesota study (Korgeski and Leon) that found the uncertainties of Agent Orange exposure produced psychological problems akin to those of survivors of atomic explosions.

Legal and political solutions

How will society respond to these newly discovered, newly perceived, and newly disputed risks? One clear trend is to move them into the courts, and Sheila Birnbaum, associate dean and professor at the New York University School of Law, said, "Given the dramatic increase in the number of claims arising from exposure to toxic substances, I wonder whether the legal system as we know it can respond. . . . There are thousands of claimants instituting action as a result of exposure to hazardous waste leaking from disposal sites, such as Love Canal and Times Beach. The potential class members in the Agent Orange case may be in the tens of thousands. Eight thousand claimants have joined in one suit for alleged injuries from exposure to DDT in northern Alabama. And asbestos certainly ranks as one of the most momentous problems in the U.S. courts: 24,000 claimants through March 1983, with 75,000 to 240,000 potential claimants; over $1 billion paid out between 1970 and 1982; a national class action now forming in Philadelphia, with the potential for sweeping in thousands of school districts; and beyond that there are 800,000 public buildings to be inspected."


Sheila Birnbaum

"Given the dramatic increase in the number of claims arising from exposure to toxic substances, I wonder whether the legal system as we know it can respond. . . . How can we design a system that will not stifle innovation, be efficient, nonbankrupting, and still compensate?"

Toxic tort litigation, according to Birnbaum, is presenting the legal system with some new issues, ones that she thinks will take perhaps a decade to work out. First, there are large numbers of plaintiffs, and in the case of generic products, perhaps thousands of plaintiffs suing hundreds of companies. Second, there are new kinds of injuries, injuries that may take 5–30 years to show up, perhaps well after the statute of limitations has run out (e.g., New York State barred the Brooklyn shipyard workers who were exposed to asbestos in the 1940s from filing claims). Third, there is the difficulty of establishing a causal link between the plaintiffs' injuries and the substance produced by the defendants.

In the way of movement toward resolving these issues, Birnbaum said, "I think we are beginning to see a judicial trend toward providing funds for long-term medical monitoring of a population exposed to hazardous substances. Further, some legislators are proposing some type of modified no-fault system, where the first recourse is to an administrative system that would provide a sliding scale for compensation and put a cap on damage awards, much like workmen's compensation. Only after that would there be recourse to the courts."

On a more philosophic plane, she added, "Regarding future injury, we are at a real legal crossroads: Should we give an award today for possible damage 20 years down the road? Or should we modify statutes of limitation to allow awards to those actually injured 20 years from now? How can we design a system that will not stifle innovation, be efficient, nonbankrupting, and still compensate?"

The legal issues drew some of the greatest heat of the conference. Floyd Culler, president of EPRI, weighed in, "I

can't imagine paying for risk. Where would it stop? For that matter, where would it begin?" Ames, following this logic said, "Ordinary mustard has a carcinogen in it. Can these people sue the mustard manufacturers? Should we compensate people for eating mustard?" And Michael Gough, senior associate with the Office of Technology Assessment, held out for compassion as a guideline for reason. "People whose children suffer birth defects should get more than people with sleepless nights from worry." Birnbaum agreed that "anxiety is fraught with false claims, and if we as a society pay, we encourage worry."

Toxic torts has become big business, and many participants singled out greed as a real driving force behind the rush to the courts. Most of the ire was directed at the legal profession, who, in the case of the asbestos awards, have walked away with sixty cents on the dollar. Peter Huber, law clerk with the U.S. Supreme Court, added, "This ignores the cost of the courts themselves, the bureaucracies, the larger legal machinery. The laws of risk have become grossly disconnected from science, and partly because the business is so tremendously lucrative." As if to add insult to injury, Birnbaum noted that foreign plaintiffs, unable to collect in their own countries, are now coming to the United States for recovery.

The regulatory role

Regulatory agencies, not unlike the courts, have become lightning rods for public dissension over technological risk. Russell characterizes EPA as a product of three forces: law, science, and public pressure. "We're not philosopher-kings who can sit aside in an ivory tower. We must act under the law, that is, under 12 major statutes passed by Congress under different circumstances, with different motivations, and with different ends in view. Some of these statutes, such as the Toxic Substances Control Act, allow us to balance risks, to weigh the costs and benefits of alternatives, and to come to some reasoned decision. But others, such as part of the Clean Air Act, have no risk-balancing provisions and they say, in effect, that we should have zero risk, which is clearly impossible.

"So we need some flexibility to operate. But now the mood of the country and the mood of Congress is to eliminate all that flexibility. We have, for example, 300 past and current statutory deadlines, many of which are simply impossible for us to meet in terms of getting the science done, getting the work done, and putting it together. As a result, we are constantly in violation of the law, and anybody can sue us. And when they do, any judge who wishes to do so can find reason on behalf of the plaintiff to set us off on a court-ordered schedule. So we now find ourselves constantly working on somebody else's agenda and redirecting our resources to the next court-ordered deadline."

Milton Russell

"The EPA is a product of three forces: law, science, and public pressure. We're not philosopher-kings who can sit aside in an ivory tower. We must act under the law, that is, under 12 major statutes passed by Congress under different circumstances, with different motivations, and with different ends in view."

The whipsaw comes not just from court action. Just how quickly the contagion of fear can turn about the agency's attention and resources was evident in the EDB case. Russell said, "Despite the lack of clear scientific evidence defining the magnitude of public risk, we were suddenly facing a firestorm of protest around the country. State after state was adopting nondetect levels or one-part-per-billion levels as far as food was concerned, and we were heading, through panic, ignorance, and serious concern, toward the possible disturbance of a sizable fraction of the nation's food supply. We were forced under those circumstances to act, and now we are having to move as rapidly as we can to examine the risks of alternative fumigants and pesticides."

To a nation beset with fear and splintered by special interests, the reality of limited public health resources is becoming harder to grasp or at least to accept. Averting one risk may well mean pulling resources away from another risk where the public health dollars can save more lives. Addressing this dilemma, Merril Eisenbud, director of the Laboratory for Environmental Studies at New York University Medical Center, said, "I wish we could somehow achieve a national consensus on what constitutes trivial risk so we could avoid diverting scarce public health funds. Let me give an example of a plant producing elemental phosphorus. It turns out that the radium in the phosphate rock was being converted in the process to polonium 210, which came off the stack and posed a small risk to the residents 80 kilometers downwind. The Office of Radiation Programs recommended that a special scrubber be installed that would avert 0.01 cancer deaths per year, or 1 per 100 years, at an equivalent cost of $200-$300 million dollars. Now people in the public health field are not accustomed to spending $200 million to avert one case of anything. I remind you that the total cost of the U.S. measles eradication program was less than $100 million dollars."

Russell responded that because of the public and statutory realities now facing EPA and requiring it to take action, "we have been presented with serious proposals to take risk-reduction actions in

the neighborhood of $200 million per life saved." He said he believed the real reason this was occurring was that the two models of health care in the world today, the private physician model and the public health model, were being confused. "When I go to my doctor, I'm looking for individual care. I want my physician to be my advocate, and I'm not interested in hearing that somebody across town could make better use of the medical facilities than I could. Unfortunately, this private physician model—where alternative uses of resources are not considered—is now being carried over to public health."

Perceptions and politics

With the courts clogged and the health agencies overwhelmed, public opinion and political process were of keen interest to the participants. How is public opinion on matters of risk being formed? And what role does science play in the public appraisal of risk? Stanley Rothman, professor of government at Smith College, suggested some fundamental shifts have been occurring, including "a loss of authority of the scientific establishment over the last 15 to 20 years on issues of risk; the loss of trust in scientists associated with business; and the growth of a plethora of public interest groups that have a relatively high level of credibility with the public on matters of technology and risk."

Stanley York, commissioner on the Wisconsin Public Service Commission, laid out three elements of what he called political reality affecting risk decision making. "First, the public believes that it understands the technical issues of carcinogens and nuclear power as well as anybody at this table because they have read about them in the newspaper. Second, each new study (of carcinogens) proves to the public anew that those who are making the product under discussion are indeed evil people. Third, inflammatory issues are the lifeblood of some interest groups; they will not survive without them."

Rothman takes the point even further. From data gathered in his large-scale study of social leadership in the United States, he concluded, "Political ideology has played a significant role in changing the American perception of risk over the last 20 years. To put it bluntly, some are using risk as a surrogate to attack the economic and political system of the United States."

Rothman's work to date has concentrated on attitudes toward nuclear power, but he believes that as he progresses into the area of carcinogens the basic tenets will hold up. One that he found was a strong left-right ideology dimension to the perception of nuclear safety. He examined a large number of social variables (e.g., age, sex) to explain the wide range in safety estimates, and found the only factor that correlated highly with the belief in the safety of nuclear plants is political ideology. The more liberal (or left) an individual, the more likely he or she is to believe that nuclear plants are unsafe.


Stanley Rothman

"Political ideology has played a significant role in the changing American perception of risk over the last 20 years. To put it bluntly, some are using risk as a surrogate to attack the economic and political system of the United States."

Another key finding Rothman addressed is that the public believes the scientific community is deeply divided in their opinions about nuclear power. Sixty percent of the public, for example, believe that scientists are evenly split on matters of nuclear energy, whereas he found a strong consensus among scientists that nuclear power is safe. Among individuals in the 71 disciplines in his energy expert sample, he found 88% believe nuclear plants to be safe; and among nuclear energy experts, defined broadly enough to include radiologic health and radiation genetics, he found 91% believe nuclear plants to be safe.

Rothman suggests that the public receives improper signals on the extent and nature of disagreement among scientists through the concentration of the media on the scientific minority who are political activists, those who are more inclined to speak directly to the public on matters outside of their specialty. "Traditional scientists," Rothman says, "generally don't communicate with the public. They tend to avoid public controversy because they dislike messy emotional relationships and they find it difficult to refute charges of possible disaster."

Chastising his fellow scientists on this point, Don Ritter, congressman from Pennsylvania, said, "The fray has entered the highest levels of American politics, and there is indeed a left-right breakdown on these issues. If the values of science are off on the sidelines watching, and only the values of the activists are entered into the debate, we're not going to get a balanced decision."

Ahmed rejoined this line of discussion saying he did not believe that environmental groups have had disproportionate influence in the political process, and he cautioned against the temptation to stereotype: "Environmentalists do not have a single voice. There are many different points of view, and we are not trying to do industry in. Environmentalists are not crazies. We are more than willing to make trade-offs."

Edward Larkin, commissioner with the New York Public Service Commission, observed, "What really divides us,

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here and elsewhere, what frustrates us, what prevents effective action, is the conflict of specialization and special interest. The economist, the scientists of every kind—everybody has his own narrow focus, and everybody thinks his is the most important. We don't deal in overall solutions."

Toward a new language

Quantitative risk assessment seemed to offer the participants the best hope of reaching common ground, of integrating the work of various specialists, and of putting risks into perspective. But can that perspective be communicated broadly? Walter Marshall, chairman of the Central Electricity Generating Board in the United Kingdom, remarked, "There is a third element needed, one between risk assessment and risk management, and that is presentation, the obligation to present the risk in terms that people can understand."

Don Ritter

"The fray has entered the highest levels of American politics, and there is indeed a left-right breakdown on these issues. If the values of science are off on the sidelines watching, and only the values of the activists are entered into the debate, we're not going to get a balanced decision."

A new language is needed that converts probabilistic risk assessment, with its notions of chance, into meaningful terms, and several participants offered some images for starters. North said, "We must get away from the black-and-white notions that something is either a carcinogen or it is not. I would suggest a traffic light model with red, green, and blinking amber—where we have grounds for suspicion but not enough for regulation." And Marshall offered the analogy of "one puff per Sunday. The risk you take if you smoke one-twentieth of one cigarette every Sunday is less than that of involuntary smoking, or that of one rem of radiation to each of 10 million people, or that of breathing gasoline vapors while filling up your own car once a week."

Broad public understanding was never more important, because new forms of information are likely to be put into the public forum. Upton reminded everyone that "a bill was just passed that requires the Secretary of Health and Human Services to provide Congress with a report that would include a series of tables specifying in precise numbers the probability that a cancer arising in an irradiated individual resulted from the radiation exposure, ranging from a millirad to a thousand rads. This obviously goes way beyond the science we have today. We don't know if a millirad will do anything; we don't know that a rem will do anything. But this set of tables is being produced and will be available to the public soon."

The question is not whether quantification of risk is desirable; both the public and the experts largely agree that hard numbers offer the best tool for evaluating risks and the best underpinning for a needed new language of risk. The question is whether numbers that are less than hard, and perhaps even misleading when expressed as a single value, will do more harm than good. On the positive side, they might at least add some information about potency to the label carcinogen when discussing risk in news accounts.

Looking ahead Upton says, "The real risk with releasing this table is that it will set a precedent. People will take the numbers as meaning more than they really do. And there will be the temptation to extend the rationale to chemicals, where the uncertainties of transpecies and transdose extrapolations are so vast. I see an enormous nest of problems coming on the quantification issue. But I remain dedicated to the cause because without quantification the cause is lost." ■

Karim Ahmed

"Environmentalists do not have a single voice. There are many different points of view, and we are not trying to do industry in. Environmentalists are not crazies. We are more than willing to make trade-offs."